

Notice of Allowability

Application No.

09/993,371

Examiner

Michael M. McGaw

Applicant(s)

BAEKKESKOV ET AL.

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's Response filed 18 October 2004.
2. ☒ The allowed claim(s) is/are 15.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The rejection of Claim 15 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ko et al. ***is withdrawn*** in light of (1) Applicant's amendment to the claim and (2) Applicant's arguments. See the sections "Response to Arguments" and "Allowable Subject Matter" immediately below.

The rejection of Claim 15 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pak et al. ***is withdrawn*** in light of (1) Applicant's amendment to the claim and (2) Applicant's arguments. See the sections "Response to Arguments" and "Allowable Subject Matter" immediately below.

The rejection of Claim 15 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DeAizpurua, et al. ***is withdrawn*** in light of (1) Applicant's amendment to the claim and (2) Applicant's arguments. See the sections "Response to Arguments" and "Allowable Subject Matter" immediately below.

Response to Arguments

Applicant's arguments, see pages 3-5, filed 18 October 2004, with respect to claim 15 have been fully considered and are persuasive. The rejection of claim 15 has been ***withdrawn*** pursuant to Applicant's arguments and amendment of claim 15.

Allowable Subject Matter

Claim 15 is ***allowed***.

The following is an examiner's statement of reasons for allowance:

Claim 15 has been amended to recite the limitation of "a broad band on an SDS polyacrylamide gel indicative of heterogeneity in size and or charge..." This limitation distinguishes the 38kD antigen from those of the prior art. Support for the limitation is found in figures 1 and 2 of the specification. For instance, in figure 2, lanes 2 and 5, the 38kD antigen is observed to run in a broad band. In contrast, GAD65 β runs as a sharper band. (See also page 12, final paragraph, of the specification for support for the limitation) While the term "broad" is a relative term, it is considered adequately descriptive given Applicant's use of the term on page 6 of the specification and the demonstration of the migration pattern by Applicant in the specification. Moreover, as indicated in the Declaration of Dr. Baekkeskov, others have demonstrated that Applicant's 38kD protein reproducibly exhibits this property. In contrast to Applicant's 38kD antigen, the reference 38kD protein of Ko et al. (1991) *Diabetologia* is shown to run as a sharp band. (See for instance fig. 1 on page 550). Similarly, the 38 kD antigen of Pak et al. (1990) *Diabetologia* is distinguishable as a sharp band on SDS PAGE. (See fig. 2, page 571)

In addition, it is noted that Applicant has amended the claim to include the limitation that the purified protein specifically binds to autoantibodies *present in a subgroup of prediabetic individuals and diabetic individuals at the clinical onset of*

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disease where the amended portion is indicated by the text in italics. Support for the amendment is found by the Examiner in table 2 on page 17 and on page 6 of the specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. McGaw whose telephone number is (571) 272-2902. The examiner can normally be reached on Monday through Friday from 8 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

JAMES HOUSEL
SUPERVISOR/ART UNIT 1648
TECHNOLOGY CENTER 1000

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

m. m.

Michael M. McGaw
Thursday, January 20, 2005

James C. Houder
JAMES C. HOUDER
1/24/05
COMMERCIAL PATENT EXAMINER
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